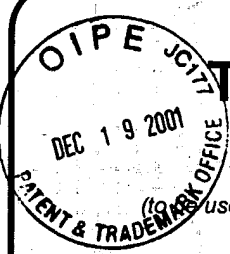


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|                                                                                                                                         |                      |                        |            |
|-----------------------------------------------------------------------------------------------------------------------------------------|----------------------|------------------------|------------|
|  <h1 style="text-align: center;">TRANSMITTAL FORM</h1> | Application Number   | 09/549,858             |            |
|                                                                                                                                         | Filing Date          | 04/14/2000             |            |
|                                                                                                                                         | First Named Inventor | McShane                |            |
|                                                                                                                                         | Group Art Unit       | 1614                   |            |
|                                                                                                                                         | Examiner Name        | Jones, D.              |            |
| Total Number of Pages in This Submission                                                                                                | 11                   | Attorney Docket Number | 109536-132 |

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| ENCLOSURES (check all that apply)                                            |                                                                                                       |                                                                                            |
|------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
| <input checked="" type="checkbox"/> Fee Transmittal Form                     | <input type="checkbox"/> Assignment Papers (for an Application)                                       | <input type="checkbox"/> After Allowance Communication to Group                            |
| <input type="checkbox"/> Fee Attached                                        | <input type="checkbox"/> Drawing(s)                                                                   | <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences        |
| <input type="checkbox"/> Amendment / Reply                                   | <input type="checkbox"/> Licensing-related Papers                                                     | <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) |
| <input type="checkbox"/> After Final                                         | <input type="checkbox"/> Petition                                                                     | <input type="checkbox"/> Proprietary Information                                           |
| <input type="checkbox"/> Affidavits/declaration(s)                           | <input type="checkbox"/> Petition to Convert to a Provisional Application                             | <input type="checkbox"/> Status Letter                                                     |
| <input type="checkbox"/> Extension of Time Request                           | <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address               | <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):            |
| <input type="checkbox"/> Express Abandonment Request                         | <input type="checkbox"/> Terminal Disclaimer                                                          |                                                                                            |
| <input checked="" type="checkbox"/> Information Disclosure Statement         | <input type="checkbox"/> Request for Refund                                                           |                                                                                            |
| <input type="checkbox"/> Certified Copy of Priority Document(s)              | <input type="checkbox"/> CD, Number of CD(s) _____                                                    |                                                                                            |
| <input type="checkbox"/> Response to Missing Parts/Incomplete Application    | Remarks                                                                                               |                                                                                            |
| <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 | - PTO Form 1449<br>- 11 References<br>- International Search Report<br>- Hand Delivery Return Receipt |                                                                                            |

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

|                         |                                 |
|-------------------------|---------------------------------|
| Firm or Individual name | Hollie L. Baker Reg. No. 31,321 |
| Signature               | <i>Hollie L. Baker</i>          |
| Date                    | <i>December 18, 2001</i>        |

## CERTIFICATE OF MAILING

|                                                                                                                                                                                                                                                                                                                                                                     |  |      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|------|
| I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on this date: <span style="border: 1px solid black; display: inline-block; width: 100px; height: 1.2em; vertical-align: middle;"></span> |  |      |
| Typed or printed name                                                                                                                                                                                                                                                                                                                                               |  |      |
| Signature                                                                                                                                                                                                                                                                                                                                                           |  | Date |

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**FEE TRANSMITTAL  
for FY 2002**

Patent fees are subject to annual revision.

AMOUNT OF PAYMENT

(\$) 180.00

**Complete if Known**

|                      |            |
|----------------------|------------|
| Application Number   | 09/549,858 |
| Filing Date          | 04/14/2000 |
| First Named Inventor | McShane    |
| Examiner Name        | Jones. D.  |
| Group Art Unit       |            |
| Attorney Docket No.  | 109536-132 |

**METHOD OF PAYMENT**

1. ☒ The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to:

Deposit Account Number **08-0219**  
Deposit Account Name **Hale and Dorr LLP**

☒ Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17

☐ Applicant claims small entity status. See 37 CFR 1.27

2. ☐ **Payment Enclosed:**

☐ Check ☐ Credit card ☐ Money Order ☐ Other

**FEE CALCULATION****1. BASIC FILING FEE**

| Large Entity |          | Small Entity |          | Fee Description        | Fee Paid |
|--------------|----------|--------------|----------|------------------------|----------|
| Fee Code     | Fee (\$) | Fee Code     | Fee (\$) |                        |          |
| 101          | 740      | 201          | 370      | Utility filing fee     |          |
| 106          | 330      | 206          | 165      | Design filing fee      |          |
| 107          | 510      | 207          | 255      | Plant filing fee       |          |
| 108          | 740      | 208          | 370      | Reissue filing fee     |          |
| 114          | 160      | 214          | 80       | Provisional filing fee |          |

SUBTOTAL (1) (\$)

**2. EXTRA CLAIM FEES**

| Total Claims       | Extra Claims | Fee from below | Fee Paid |
|--------------------|--------------|----------------|----------|
| Independent Claims | -20** =      | X              |          |
| Multiple Dependent | -3** =       | X              |          |

| Large Entity |          | Small Entity |          | Fee Description                                            |
|--------------|----------|--------------|----------|------------------------------------------------------------|
| Fee Code     | Fee (\$) | Fee Code     | Fee (\$) |                                                            |
| 103          | 18       | 203          | 9        | Claims in excess of 20                                     |
| 102          | 84       | 202          | 42       | Independent claims in excess of 3                          |
| 104          | 280      | 204          | 140      | Multiple dependent claim, if not paid                      |
| 109          | 84       | 209          | 42       | ** Reissue independent claims over original patent         |
| 110          | 18       | 210          | 9        | ** Reissue claims in excess of 20 and over original patent |

SUBTOTAL (2) (\$)

\*\*or number previously paid, if greater; For Reissues, see above

**FEE CALCULATION (continued)****3. ADDITIONAL FEES**

| Fee Code | Large Entity Fee (\$) | Small Entity Fee Code | Small Entity Fee (\$) | Fee Description                                                            | Fee Paid |
|----------|-----------------------|-----------------------|-----------------------|----------------------------------------------------------------------------|----------|
| 105      | 130                   | 205                   | 65                    | Surcharge - late filing fee or oath                                        |          |
| 127      | 50                    | 227                   | 25                    | Surcharge - late provisional filing fee or cover sheet                     |          |
| 139      | 130                   | 139                   | 130                   | Non-English specification                                                  |          |
| 147      | 2,520                 | 147                   | 2,520                 | For filing a request for <i>ex parte</i> reexamination                     |          |
| 112      | 920*                  | 112                   | 920*                  | Requesting publication of SIR prior to Examiner action                     |          |
| 113      | 1,840*                | 113                   | 1,840*                | Requesting publication of SIR after Examiner action                        |          |
| 115      | 110                   | 215                   | 55                    | Extension for reply within first month                                     |          |
| 116      | 400                   | 216                   | 200                   | Extension for reply within second month                                    |          |
| 117      | 920                   | 217                   | 460                   | Extension for reply within third month                                     |          |
| 118      | 1,440                 | 218                   | 720                   | Extension for reply within fourth month                                    |          |
| 128      | 1,960                 | 228                   | 980                   | Extension for reply within fifth month                                     |          |
| 119      | 320                   | 219                   | 160                   | Notice of Appeal                                                           |          |
| 120      | 320                   | 220                   | 160                   | Filing a brief in support of an appeal                                     |          |
| 121      | 280                   | 221                   | 140                   | Request for oral hearing                                                   |          |
| 138      | 1,510                 | 138                   | 1,510                 | Petition to institute a public use proceeding                              |          |
| 140      | 110                   | 240                   | 55                    | Petition to revive - unavoidable                                           |          |
| 141      | 1,280                 | 241                   | 640                   | Petition to revive - unintentional                                         |          |
| 142      | 1,280                 | 242                   | 640                   | Utility issue fee (or reissue)                                             |          |
| 143      | 460                   | 243                   | 230                   | Design issue fee                                                           |          |
| 144      | 620                   | 244                   | 310                   | Plant issue fee                                                            |          |
| 122      | 130                   | 122                   | 130                   | Petitions to the Commissioner                                              |          |
| 123      | 50                    | 123                   | 50                    | Processing fee under 37 CFR 1.17(q)                                        |          |
| 126      | 180                   | 126                   | 180                   | Submission of Information Disclosure Stmt                                  | 180.00   |
| 581      | 40                    | 581                   | 40                    | Recording each patent assignment per property (times number of properties) |          |
| 146      | 740                   | 246                   | 370                   | Filing a submission after final rejection (37 CFR § 1.129(a))              |          |
| 149      | 740                   | 249                   | 370                   | For each additional invention to be examined (37 CFR § 1.129(b))           |          |
| 179      | 740                   | 279                   | 370                   | Request for Continued Examination (RCE)                                    |          |
| 169      | 900                   | 169                   | 900                   | Request for expedited examination of a design application                  |          |

Other fee (specify)

\*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$) 180.00

**SUBMITTED BY**

Complete (if applicable)

|                   |                        |                                   |            |           |              |
|-------------------|------------------------|-----------------------------------|------------|-----------|--------------|
| Name (Print/Type) | Hollie L. Baker        | Registration No. (Attorney/Agent) | 31,321     | Telephone | 617-526-6110 |
| Signature         | <i>Hollie L. Baker</i> | Date                              | 12-18-2001 |           |              |

**WARNING:** Information on this form may be made public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

(109536.132)

Applicant: McShane et al.

Serial No.: 09/549,858

Filing Date: April 14, 2000

Title: **Pharmaceutical Formulation Comprising  
Glycine as a Stabilizer**

Art Unit: 1614

Examiner: Jones, D.

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Assistant Commissioner for Patents  
Washington, D.C. 20231

Via Hand Delivery

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. § 1.97, Applicants submit the references listed on the attached PTO Form 1449. The submission of this statement is not a representation that a search has been made, or that no better or other relevant art exists. This submission is also not an admission that any of the cited references is, or is considered to be, material to patentability or that any of the cited references constitutes prior art to the invention. Moreover, the Applicants understand that the Examiner will make an independent evaluation of the cited publications.

This application is a 35 U.S.C. § 371 application of PCT application serial no. PCT/US98/21972, filed September 14, 1998, which claims priority under 35 U.S.C. § 119(e) of provisional U.S. patent application serial no. 60/062,089, filed October 14, 1997.

Copies of all references listed on the attached PTO Form 1449, other than those discussed below, are enclosed herewith.

Copies of the following references are not enclosed herewith as these references were cited by the Examiner on a Form PTO-892. However, copies can be provided upon request.

1. U.S. Patent No. 5,045,552, Souda et al.
2. Osol et al., Editor-in-chief of Remington's Pharmaceutical Sciences, 15<sup>th</sup> Edition, page 963, June 11, 1976.

A copy of the PCT International Search Report for PCT/US98/21972, the PCT application of which this application is a 35 U.S.C. § 371 application, is also enclosed herewith. The first citation in the International Search Report lists two Japanese applications:

1. JP 05 194225 (8/3/1993)
2. JP 00 594225

Copies of the abstracts for these Japanese applications were not available at this time. However, Applicants will provide copies upon request.

The International Search Report also lists a German publication, which is entirely in German.

1. DE 30 00 743 A

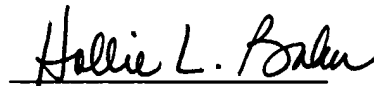
As this publication is in German, Applicants have listed on the PTO Form-1449 and submitted herewith U.S. Patent No: 4,265,888, which is listed in the same family in the International Search Report. However, Applicants will provide a copy of the German publication and a translation, if necessary, upon request.

This statement is being filed after a first Office Action on the merits, but before the receipt of a final Office Action or a Notice of Allowance. Please charge our Deposit Account No. 08-0219 the required fee of \$180.00 pursuant to 37 C.F.R. § 1.17(p).

No other fees are believe to be due in connection with this submission. However, please charge any underpayments or credit any overpayments to Deposit Account No. 08-0219.

Respectfully submitted,

HALE AND DORR LLP

A handwritten signature in black ink, reading "Hollie L. Baker". The signature is written in a cursive style and is positioned above a horizontal line.

Hollie L. Baker  
Registration No. 31,321  
Attorney for Applicant

60 State Street  
Boston, MA 02109  
(617) 526-6000  
(617) 526-5000 (fax)

Date: December 18, 2001